SEP 2 8 2011

Section 5. 510(k) Summary

510k Number: K103217

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

LITE-MED LM-9200 ELMA Lithotripter

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the LM-9200 ELMA is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices like Dornier Compact Alpha Lithotripter (K002929), Siemens Lithoskop (K070665) and Medispec Econolith EM1000 (K063504).

Applicant/Manufacturer Information

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TAIWAN
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Device Identification

Proprietary Trade Name:	LM-9200 ELMA
Generic Device Name:	Extracorporeal Shockwave Lithotripter
Product Code:	78 LNS
Regulatory Class:	Class II with special controls
Regulation Number:	21 CFR 876.5990

Intended Use

The Lite-Med LM-9200ELMA Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle, and lower ureteral stones.

Substantial Equivalence

The Lite-Med LM-9200ELMA Lithotripter is substantially equivalent to the following currently marketed devices:

Dornier Compact Alpha Lithotripter
Siemens Lithoskop
Medispec Econolith EM1000

Device Description

The Lite-Med LM-9200 ELMA is an Electromagnetic Extracorporeal Shock Wave Lithotripter that effectively treats urinary calculi. It is routinely used for the fragmentation of kidney and ureteral stones and offers a good combination of clinical performance, flexibility and affordability. The standard LM-9200 ELMA device consists of a Shockwave Generator, an operator interface/touch panel, and a water circulation subsystem. Shock waves are generated on the basis of a principle similar to that used in loudspeakers. An electrical impulse is sent through an inductance coil, generating a magnetic field which repulses a metallic membrane. The acoustic impulse created by this repulsion is focused by an acoustic lens to form a shock wave. A water circulation subsystem is used to provide transmission of shockwaves and cooling of the generator.

For the ESWL operation to be fully functional, two or three optional subsystems are needed. The first is a special treatment table. The second and third are a C-arm X-ray fluoroscope and an ultrasound imaging unit. The treatment table is a motorized floating table which can be moved electrically in all three axes.

Technological Characteristics

The shock wave characteristics are reported below by taking the guideline described in the consensus standard IEC 61846 "Ultrasonics – Pressure pulse lithotripters – Characteristics of fields" (1998) into consideration. PVDF film type hydrophones are used in the measurements. The details of the measurements/calculations are given in relevant part of 510(k) application. The results are found similar to the predicate device characteristics.

Parameter	min(16kv)	typical(18kv)	max(20kv)
Peak-positive acoustic pressure(MPa)	17.7	29.2	35.6
Peak-negative acoustic pressure(MPa)	3.2	3.5	3.2
Rise time (ns)	400	200	100
Compressional pulse duration(ns)	400	400	360
Maximum focal width(mm)	7	7.5	8
Orthogonal focal width(mm)	7	7.5	8
Focal extent(mm)	106	125	120
Focal volume(mm3)	2720	3682	4021
Distance between the focus and target location(mm) –z-axis	3	3	3
Distance between the focus and target location(mm) –x/y-axis	2	2	2
Derived focal acoustic pulse energy(mJ)	3.08	5.25	7.62
Derived acoustic pulse energy(mJ) (R=12mm)	5.93	9.81	13.31

Clinical Study

The clinical investigations are performed at 2 sites with 1 and 2 weeks follow-up to support this application. Totally 40 (30 male, and 10 female) patients with stones were treated. The stones sizes treated were between 5 mm and 18 mm. None of the patients received general anesthesia. The overall success rate of the investigations is measured as 85%.

The experiences of physicians have shown that patients treated by the LM-9200 ELMA are safe and having high evaluations for the device function. And the user's manual is adequate for the operation of LM-9200 ELMA. The incidence of device malfunction does not happen in these clinical investigations.

Safety and Performance Studies

The LM-9200 ELMA is designed in accordance with the product safety and performance requirements established in the following standards :

IEC 60601-2-36	Particular Requirements for safety of equipment for extracorporeally induced lithotripsy
IEC 61846	Ultrasonics – Pressure pulse lithotripters – Characteristics of fields (1998)
IEC 60601-1-1	Medical Electrical Equipment – Part 1 General Requirements for Safety" with Amend 1 and 2
IEC 60601-1-2	Medical Electrical Equipment – Part 1 General Requirements for Safety-2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests
IEC 60601-1-4	Medical Electrical Equipment – Part 1 General Requirements for Safety-4. Collateral Standard: Programmable Electrical Medical Systems
ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971	Medical Devices – Application of Risk Management to Medical Devices

Conclusion

From a clinical perspective and comparing design specifications, the LM-9200 ELMA is substantially equivalent to the predicate devices. The LM-9200 ELMA meets the FDA requirements stated in "Guidance for the Content of Premarket Notifications 510(k)s for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" issued on Aug. 9, 2000. Lite-Med Inc. believes the minor differences of the LM-9200 ELMA and its predicate devices should not raise any concerns regarding the overall safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Walt Hsu
President and CEO
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TAIPEI CITY 110 TAIWAN R.O.C.

SEP 28 2011

Re: K103217
Trade/Device Name: LM-9200 ELMA
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: September 23, 2011
Received: September 26, 2011

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K103217
Device Name: LM-9200 ELMA
Indications for Use:

The Lite-Med LM-9200ELMA Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper, middle, and lower ureteral stones.

Prescription Use x AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103217